

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Dr. Richard Trepeta, M.D.)

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Defendant's Motion to Exclude the Opinions and Testimony of Richard W. Trepeta, M.D. filed by Boston Scientific Corporation ("BSC"). [ECF No. 4811]. The Motion is now ripe for consideration because the briefing is complete. As set forth below, BSC's Motion is **GRANTED**.

I. Background

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the BSC MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court’s role as gatekeeper is an important one. “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v.*

Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We

agree with the Solicitor General that “[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.” (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Trepeta is a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease. BSC argues that Dr. Trepeta’s method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his expert opinion: (1) He has studied over fifty mesh explant samples in his private practice; (2) he has studied the medical literature on mesh implantation and determined that his pathological findings corresponded with the published research on mesh erosion and exposure in the vaginal wall; and (3) he has reviewed twenty-four pathology reports that he received from plaintiffs’ counsel and ascertained that

the pathology reports of excised Boston Scientific products are consistent with the acute, sub-acute, and chronic categories of the disease process.

Dr. Trepeta's review of the pathology reports has a fatal deficiency—it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. The plaintiffs do not explain how or why she chose these twenty-four reports for Dr. Trepeta's review. Without such an explanation, I have no way of assessing the potential rate of error or the presence of bias. Accordingly, Dr. Trepeta's opinions derived solely from his review of the twenty-four pathology reports are **EXCLUDED**. BSC is free to cross-examine Dr. Trepeta at trial to ensure that the basis of his opinions is consistent with the court's ruling. Accordingly, BSC's Motion is **GRANTED**.

IV. Conclusion

To summarize, BSC's *Daubert* Motion concerning Dr. Trepeta [ECF No. 4811] is **GRANTED**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

| Case Number | Case Name |
|---------------|---|
| 2:17-cv-00047 | Long v. Boston Scientific Corporation |
| 2:17-cv-00049 | Parker et al v. Boston Scientific Corporation |
| 2:17-cv-00294 | Grigg v. Boston Scientific Corporation |
| 2:17-cv-00304 | Martinez v. Boston Scientific Corporation |
| 2:17-cv-00307 | Michael v. Boston Scientific Corporation |
| 2:17-cv-00314 | Newton v. Boston Scientific Corporation |
| 2:17-cv-00315 | Norris v. Boston Scientific Corporation |
| 2:17-cv-00317 | Norris v. Boston Scientific Corporation |
| 2:17-cv-00318 | Osborn v. Boston Scientific Corporation |
| 2:17-cv-00325 | Pick v. Boston Scientific Corporation |
| 2:17-cv-00528 | Sustaita v. Boston Scientific Corporation |
| 2:17-cv-00534 | Notestine v. Boston Scientific Corporation |
| 2:17-cv-00536 | Sutiff v. Boston Scientific Corporation |
| 2:17-cv-00568 | Mahnke v. Boston Scientific Corporation |
| 2:17-cv-00701 | Babcock v. Boston Scientific Corporation |
| 2:17-cv-01074 | Dembski v. Boston Scientific Corporation |
| 2:17-cv-01098 | Zeiter v. Boston Scientific Corporation |

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| 2:17-cv-01109 | Herbert et al v. Boston Scientific Corporation |
| 2:17-cv-01241 | Tigner v. Boston Scientific Corporation |
| 2:17-cv-01242 | Evans v. Boston Scientific Corporation |
| 2:17-cv-01243 | Brown v. Boston Scientific Corporation |
| 2:17-cv-01837 | Allen v. Boston Scientific Corporation |
| 2:17-cv-01845 | Shiflet v. Boston Scientific Corporation |
| 2:17-cv-01862 | Faso et al v. Boston Scientific Corporation |
| 2:17-cv-01900 | Hauff et al v. Boston Scientific Corporation |
| 2:17-cv-01925 | Skalniak et al v. Boston Scientific Corporation |
| 2:17-cv-01932 | Peach v. Boston Scientific Corporation |
| 2:17-cv-01938 | Schroder v. Boston Scientific Corporation |
| 2:17-cv-01939 | Price v. Boston Scientific Corporation |
| 2:17-cv-01940 | Conley v. Boston Scientific Corporation |
| 2:17-cv-01959 | Lowrie v. Boston Scientific Corporation |
| 2:17-cv-01977 | Hardwick v. Boston Scientific Corporation |
| 2:17-cv-01979 | Dunford et al v. Boston Scientific Corporation |
| 2:17-cv-01990 | Hill-Sober et al v. Boston Scientific Corporation |
| 2:17-cv-01996 | Benson v. Boston Scientific Corporation |

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| 2:17-cv-02093 | Pamensky Murray v. Boston Scientific Corporation |
| 2:17-cv-02106 | Wilson v. Boston Scientific Corporation |
| 2:17-cv-02107 | Ross v. Boston Scientific Corporation |
| 2:17-cv-02110 | Clark v. Boston Scientific Corporation |
| 2:17-cv-02111 | Busby v. Boston Scientific Corporation |
| 2:17-cv-02202 | Atwood v. Boston Scientific Corporation |
| 2:17-cv-02243 | Alvarado v. Boston Scientific Corporation |
| 2:17-cv-02244 | Speed v. Boston Scientific Corporation |
| 2:17-cv-02416 | Palmer v. Boston Scientific Corporation |
| 2:17-cv-02417 | Masterson v. Boston Scientific Corporation |
| 2:17-cv-02443 | Allex v. Boston Scientific Corporation |
| 2:17-cv-02446 | Blalock v. Boston Scientific Corporation |
| 2:17-cv-02447 | Casale v. Boston Scientific Corporation |
| 2:17-cv-02448 | Clark v. Boston Scientific Corporation |
| 2:17-cv-02449 | Cole v. Boston Scientific Corporation |
| 2:17-cv-02450 | Wallace v. Boston Scientific Corporation |
| 2:17-cv-02459 | Mallory v. Boston Scientific Corporation |
| 2:17-cv-02461 | Martin v. Boston Scientific Corporation |

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| 2:17-cv-02462 | McSween v. Boston Scientific Corporation |
| 2:17-cv-02467 | Melrose v. Boston Scientific Corporation |
| 2:17-cv-02470 | Porter v. Boston Scientific Corporation |
| 2:17-cv-02471 | McFalls v. Boston Scientific Corporation |
| 2:17-cv-02477 | Pouncy v. Boston Scientific Corporation |
| 2:17-cv-02481 | Shepard v. Boston Scientific Corporation |
| 2:17-cv-02483 | Smith v. Boston Scientific Corporation |
| 2:17-cv-02486 | Daniell v. Boston Scientific Corporation |
| 2:17-cv-02505 | Cutlip v. Boston Scientific Corporation |
| 2:17-cv-02508 | Jeter v. Boston Scientific Corporation |
| 2:17-cv-02524 | Murphy v. Boston Scientific Corporation |
| 2:17-cv-02525 | Price v. Boston Scientific Corporation |
| 2:17-cv-02527 | Roark v. Boston Scientific Corporation |
| 2:17-cv-02528 | Saldivar v. Boston Scientific Corporation |
| 2:17-cv-02531 | Smith v. Boston Scientific Corporation |
| 2:17-cv-02533 | Southwood v. Boston Scientific Corporation |
| 2:17-cv-02551 | Solomon v. Boston Scientific Corporation |
| 2:17-cv-02553 | Spencer v. Boston Scientific Corporation |

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| 2:17-cv-02554 | Stark v. Boston Scientific Corporation |
| 2:17-cv-02562 | Vincent v. Boston Scientific Corporation |
| 2:17-cv-02566 | Walker v. Boston Scientific Corporation |
| 2:17-cv-02568 | Welsh v. Boston Scientific Corporation |
| 2:17-cv-02571 | Wittenborn v. Boston Scientific Corporation |
| 2:17-cv-02588 | Adams v. Boston Scientific Corporation |
| 2:17-cv-02589 | Barnett v. Boston Scientific Corporation |
| 2:17-cv-02590 | Childress v. Boston Scientific Corporation |
| 2:17-cv-02592 | Dickeson v. Boston Scientific Corporation |
| 2:17-cv-02596 | McFolling v. Boston Scientific Corporation |
| 2:17-cv-02597 | Morgan v. Boston Scientific Corporation |
| 2:17-cv-02598 | Reid v. Boston Scientific Corporation |
| 2:17-cv-02599 | Reyes v. Boston Scientific Corporation |
| 2:17-cv-02600 | Rinaldi v. Boston Scientific Corporation |
| 2:17-cv-02601 | Woodard v. Boston Scientific Corporation |
| 2:17-cv-02633 | Pierson et al v. Boston Scientific Corporation |
| 2:17-cv-02636 | Walseth v. Boston Scientific Corporation |
| 2:17-cv-02638 | Buttke v. Boston Scientific Corporation |

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| 2:17-cv-02641 | Harrison-Hood v. Boston Scientific Corporation |
| 2:17-cv-02646 | Gottfreid v. Boston Scientific Corporation |
| 2:17-cv-02730 | Black v. Boston Scientific Corporation |
| 2:17-cv-02734 | Henjum v. Boston Scientific Corporation |
| 2:17-cv-02738 | Martin v. Boston Scientific Corporation |
| 2:17-cv-02739 | Martinez v. Boston Scientific Corporation |
| 2:17-cv-02742 | Morales v. Boston Scientific Corporation |
| 2:17-cv-02745 | Shaw v. Boston Scientific Corporation |
| 2:17-cv-02787 | Stapf v. Boston Scientific Corporation |